UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,859	05/29/2002	Seishi Kato	2002-0400 A	6799

513 7590 10/09/2008

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,859	KATO ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 6* is/are pending in the application.

4a) Of the above claim(s) *1 and 2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the method of claims 5 and 6 in the reply filed on 7/7/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1 and 2 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/7/08.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed inventions. The specification discloses a method of producing an antibody using the particular steps recited in the claims, but does not disclose the claimed method which encompasses immunization for purposes other than producing an antibody (for example immunization to induce a T cell response). Regarding applicants comments and the cited passages of the specification, said passages are limited to the disclosure of a method for producing an antibody. There is no support in the specification as originally filed for the scope of the claimed invention (aka the claimed invention constitutes new matter).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholler et al. (US 2003/0008342) in view of Yokoyama-Kobayashi et al.
Scholler et al. disclose immunization with vectors that induce antibodies wherein the vectors can encode a fusion protein with an artificially added transmembrane domain (see abstract, [0022], [0053]-[0055] and [0087], [0115]). Scholler et al. disclose immunization via intradermal administration (see Example 2). The antibody response is measured in an in vitro assay wherein the sample would be isolated and purified prior to or during the assay (see [0034] and [0142]). Scholler et al. do not disclose use of the vector recited in the claims using SEQ ID NO. 2 or that the antigenic protein is fused with the c terminal of a transmembrane domain. Yokoyama-Kobayashi et al. teach the vector recited in the claims (see Figure 1(b) for a description of the peptide encoded by the vector and pages 162, sections 2.2,2.3 and page 163, section 3.2 for a description of said vector). Said vector encodes a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain (see abstract). Yokoyama-Kobayashi et al. disclose that said vector can be used to produce a fusion protein that can be used to anchor a secreted molecule to the cell surface (see abstract). It would have been prima facie obvious to one of ordinary

skill in the art at the time the invention was made to have created the claimed invention because Scholler et al. disclose immunization with vectors that induce antibodies wherein the vectors can encode a fusion protein with an artificially added transmembrane domain whilst Yokoyama-Kobayashi et al. teach a vector that encodes a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain.

Regarding applicants comments, the claims under consideration are not drawn to a method of making an antibody. The claims are drawn to a method of immunization. Boyle et al. discloses that membrane bound antigen results in **a superior CTL response** (see abstract). Thus, regarding the method under consideration (a method of immunization) Boyle et al. discloses that membrane bound antigen immunization results in a superior CTL response. Regarding applicants comments, Scholler et al. disclose that the SRA can be a secretory protein (see section [0021, line 9]). Regarding applicants comments about "concrete examples", "concrete examples" are not required to provide enablement for a US patent application or prior art reference. Regarding applicants comments about reasonable expectation of success, the MPEP section 2121[R-6] states:

2121 [R-6] Prior Art; General Level of Operability Required to Make a Prima Facie Case
I. >< PRIOR ART IS PRESUMED TO BE OPERABLE/ENABLING
When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

The prior art is enabled and thus provides a reasonable expectation of success of making the claimed invention. Applicant has not provided evidence as to why Scholler et al. is not enabled. Regarding Boyle et al., said reference is limited to studies using intramuscular injection (see abstract). The claims are drawn to methods using

intradermal administration wherein Boyle et al. does not address intradermal administration.

Furthermore, Boyle et al. actually discloses **that the antibody response seen to mOVA versus sOVA depends on the time point examined and the responses are equivalent at the time of peak response** (see page 1900, first incomplete paragraph, lines 3-8).

Boyle et al. disclose that:

"Compared to the response to sOVA, the IgG response of mOVA immunized mice was 30 fold lower at 2 weeks, but when it peaked at 8 weeks there was no significant difference from that of sOVA immunized mice (Fig, 2A) although the response in the sOVA immunized mice had reached a plateau..".

Regarding applicants comments, **the total response at 8 weeks is not significantly different as per the preceding quote from Boyle et al.**

Furthermore, Boyle et al. disclose that:

***"The IgG2a and IgG2b titers were similar between sOVA and mOVA immunized mice at all time points. Similar results were obtained in CBAXC57Bl/6 mice (data not shown)."* (page 1900, second column).**

Regarding applicants comments, as per above Boyle et al. teach that the IgG2a or IgG2b titers are similar, wherein the claimed method could be used to make antibodies specific for the aforementioned isotypes. Furthermore, regarding applicants comments about the quoted passage of the specification, said observation is clearly erroneous as applying to antibodies per se because Boyle et al. disclose that:

***"The IgG2a and IgG2b titers were similar between sOVA and mOVA immunized mice at all time points. Similar results were obtained in CBAXC57Bl/6 mice (data not shown)."* (page 1900, second column).**

Furthermore, regarding the applicability of the findings of Boyle et al. to other antigens, Boyle et al. disclose that **other researchers have found only a "slight increase" in response to immunization with secreted versus membrane bound antigen (see page 1904, column 1, lines 9-15).** Furthermore, Boyle et al. disclose that differences in

the plasmids used could potentially account for the results that they describe (see page 1904, second column, first complete paragraph).

Finally, Scholler et al. disclose immunization via the intradermal route, so the Boyle et al. reference is not germane to the instant rejection because the claims do not recite immunization via the im route and Scholler et al. disclose immunization via the intradermal route.

Regarding applicants comments, Yokoyama-Kobayashi et al. teach **the identical vector recited in the claims** (see Figure 1(b) for a description of the peptide encoded by the vector and pages 162, sections 2.2,2.3 and page 163, section 3.2 for a description of said vector). Said vector encodes **a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain** (see abstract) and wherein the protein portion is therefore expressed extracellularly. Yokoyama-Kobayashi et al. disclose that said vector can be used to produce a fusion protein that can be used to anchor a secreted molecule to the cell surface (see abstract).

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644